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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,677	03/11/2004	John Michael Green II	29997/068	6318

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MCCRACKEN & FRANK LLP
200 W. ADAMS STREET
SUITE 2150
CHICAGO, IL 60606

EXAMINER	
CHAO, ELMER M	
ART UNIT	**PAPER NUMBER**
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/798,677	GREEN ET AL.	
	Examiner	Art Unit	
	Elmer Chao	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/13/2004 & 9/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings contain hand-written numerals. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. **Claims 1-22, 54-73, and 95-110** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite the structural limitation, "finger mounted structure" or "finger mounted pointer", both which positively recite the human body. Examiner suggests the claim language be changed to "structure capable of being mounted on a finger" or "pointer adapted to be mounted on a finger". Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 1-3, 5-7, 12-18, 19, 21, 23-30, 32, 33, 39, 40-42, 49, 50, 52, 54-56, 58, 59, 65-69, 70, 72, 74-77, 79, 80, 86-93, 95, 96, 98-102, 108, and 109** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. (U.S. 6,524,260 B2) in view of Bova et al. (U.S. 6,390,982).

Regarding **Claims 1-3, 5-7, 12-16, 18, 19, 21, 23-30, 32, 39, 49, 50, 52, 54-56, 58, 59, 65-69, 72, 74-77, 79, 86-89, 92, 93, 95, 96, 98-102, 108, and 109**, Shechtman et al. teaches a system and method for determining a contour of a spine, comprising a surgical navigation system (Fig. 2, Item 10), mounting a substrate capable of being

removably mounted to an outer surface of a user's body (Fig. 4, Item 32; col. 4, lines 3-8); a magnetic tracking positional device attached to the substrate (col. 6, lines 59-63; col. 4, lines 3-8); disposing a finger mounted structure capable of communicating with the positional device (Fig. 4, Item 30), wherein the finger mounted structure is located adjacent a tip and pad of the user's finger (Figs. 2-4); a first and second circuit for calculating a position of a point on the anatomical structure by correlating a position of the sensor and a position of the finger mounted structure (Fig. 5; col. 7, lines 1-22; col. 8, lines 25-44); wherein the anatomical spine is mapped by placing the tip of the finger mounted structure on the point of the anatomical structure to be determined and concatenating the position of a plurality of points (Fig. 6a & 6b).

Shechtman et al. teaches the limitations as discussed above but fails to teach a sensor attached to the substrate that can be tracked by the surgical navigation system. However, in a related field of ultrasonic imaging Bova et al. teaches using a room as a fixed frame of reference by using an infra-red camera system, thereby permitting global positioning (Fig. 2, Item 28). Furthermore, Shechtman et al. teaches that the fingertip device can also contain an ultrasonic transducer to image the vertebrate (Fig. 12a – 12c). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to calculate global positions using the infra-red camera system and a position sensor on the substrate in the configuration of Bova et al.'s invention in order to perform therapeutic and other forms of medical procedures following a diagnosis (for motivation see Bova et al. (col. 3, lines 15-18; col. 3, lines 38-41)).

Regarding **Claims 33 and 80**, Shechtman et al. and Bova et al. teach the limitations as discussed above, but fail to teach mounting a substrate to a user's hand. However, Shechtman et al. teaches that the substrate can be used either as a reference sensor that does not move in relation to the patient's spine (col. 6, lines 42-58). Therefore, it would have been obvious for a person of ordinary skill in the art at the time of the invention to attach the substrate to a user's hand opposite the hand containing the finger mounted substrate in order for the user to ensure that the substrate maintains a fixed position relative the spine being mapped (for motivation see col. 6, lines 42-58).

Regarding **Claims 41, 42, 90, and 91**, Shechtman et al. and Bova et al. teach the limitations as discussed above, but fail to teach the user utilizing a second tool wherein the second tool saves the user time and the position of the point is determined at the same time the second tool is being used. However, Shechtman et al. teaches another embodiment wherein a display-type probe (Fig. 14 & 15, Item 70) is used in conjunction with the finger probe (col. 10, lines 5-42). Therefore, it would have been obvious for a person of ordinary skill in the art at the time of the invention to include using a second tool to determine position as described by Shechtman et al. in order to obtain rotation and/or deformation information of the apex vertebra (for motivation see col. 10, lines 29-37).

Regarding **Claims 17, 40, and 70**, Shechtman et al. and Bova et al. teach the limitations as discussed above but fail to explicitly teach the positional device switch located in the palm of a hand. However, Shechtman et al. does teach the switch being located adjacent the palm of the hand where it is assessable by the thumb (Fig. 2, Item

6). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to place the switch in the palm of the hand because such a location would be functionally equivalent as placing the switch slightly above the hand. Placing the switch in the palm of the hand as compared to Shechtman et al.'s location would serve the same purpose of keeping the switch within the reach of one of the fingers of the hand containing the device (for support see the Present Application, Specifications, page 10, top paragraph).

7. **Claims 8, 9, 11, 34-36, 38, 60-62, 64, 71, 81-83, 85, 103-105, 107,** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner (U.S. 6,746,402 B2). Shechtman et al. and Bova et al. teach the limitations as discussed above. They do not teach the tip of the finger-mounted device having a depressible tip. However, in the related field of ultrasonic imaging, Ustuner teaches a finger mountable probe with a depressible tip that will activate the ultrasound device upon sensing of contact (col. 4, lines 44-52, the tip activates upon contact and hence requires pressure to activate). Therefore, it would have been obvious to a person of ordinary skill in the art modify Shechtman et al. in view of Bova et al. to include the contact sensor tip in order to automate the turning on and off of recording the position of the sensor on the finger mounted device (for motivation see col. 4, lines 44-52).

8. **Claims 4, 10, 31, 37, 57, 63, 78, 84, 97, and 106** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al. (U.S. 6,511,427 B1).

Regarding **Claims 4, 31, 57, 78, and 97**, Shechtman et al, Bova et al., and Ustuner teach the limitations as discussed above but fail to teach tactile feedback to aid the user in maneuvering the finger mounted structure. However, in the related field of ultrasonic imaging, Sliwa, Jr. et al. teaches an ultrasonic probe with pressure-sensing transducers that provide tactile feedback (col. 8, lines 16-39; col. 5, lines 47-64). Therefore, it would have been obvious to a person of ordinary skill in the art to have included pressure sensing transducers with tactile feedback in order to prompt the user to control the force of the finger mounted device on the skin as the contour of the spine is mapped out (for motivation see col. 8, lines 16-39).

Regarding **Claims 10 and 37, 63, 84, 106**, the addition of the pressure-sensing mechanisms would create a system capable of activating and deactivating the positional device at a predefined pressure.

9. **Claims 22, 53, 73, 94, and 110** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Danisch (U.S. 5,321,257). Shechtman et al. and Bova et al. teach all of the above limitations. They do not teach the use of a fiber optic device to sense position. However, Danisch teaches the use of a single or multiple fiber optic devices to sense position (Fig. 12; col. 6, lines 20-39). Therefore, it would have been obvious to a person of ordinary skill in

the art at the time of the invention to use a fiber optic device to sense position in order to provide a temperature-resistant and dynamic range of measurement (for motivation see col. 9, lines 49-68).

10. **Claims 43, 111-126, 132, 133, 135, and 136** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al., further in view of Danisch, and further in view of Walbrink et al. (U.S. 5,449,356). Shechtman et al., Bova et al., Ustuner, Sliwa, Jr. et al., and Danisch teach all of the above limitations. They do not teach the method of making an incision in a patient's body. However, in the field of minimally invasive surgery, Walbrink et al. teaches making an incision to position a surgical tool (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to incorporate the methods of the minimally invasive probe to the finger-mounted device in order to gain access to the interior origins and tissues of the body (for motivation see col. 1, lines 5-14).

11. **Claims 44-46, and 127-129** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al., further in view of Danisch, further in view of Walbrink et al., and further in view of Magasi (U.S. 4,826,492). Shechtman et al., Bova et al., Ustuner, Sliwa, Jr. et al., Danisch, and Walbrink et al. teach all of the above limitations. They do not teach the method of making an incision with a length between 2.5 cm and

5cm. However, in the field of minimally invasive surgery, it is well-known to one skilled in the art to minimize incisions lengths (col. 1, lines 18-35). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make an incision length between 2.5 cm and 5 cm in order to be able to insert the probe attached to the user's finger while reducing the amount of discomfort and pain felt by the patient during insertion (for motivation see col. 2, lines 13-18). Furthermore, the specific choice of an incision length of 2.5cm to 5cm is considered a design choice because the Present Application does not specify a particular advantage of such a range (for support see Present Application, Para [0029]).

12. **Claims 20, 47, 48, 51, 130, 131, and 134** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al., further in view of Danisch, further in view of Walbrink et al., and further in view of Touzawa et al. (U.S. 2003/0198372A1). Shechtman et al., Bova et al., Ustuner, Sliwa, Jr. et al., Danisch, and Walbrink et al. teach all of the above limitations. They do not explicitly teach the method of making an incision to the knee, hip, or organ of a patient's body. However, in the same field of mapping contours, Touzawa et al. teaches a method for determining the contour of an organ (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make incisions at different locations on the body in order to determine the contour of an organ in order to perform quantitative analysis of the organ such as volume measurements (for motivation see Para [0002]).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC
3/30/2007

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER